UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,579	09/07/1999	SUSUMU IKEHARA	Q55691	2802

7590 11/29/2001

SUGHRUE MION ZINN MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 200373202

EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	17

DATE MAILED: 11/29/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/380,579	Applicant(s) IKEHARA ET AL.	
	Examiner Jessica H. Roark	Art Unit 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 November 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *please see attached*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: 9-12.

   Claim(s) withdrawn from consideration: _____.

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
11/29/01

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Section 5. continued.

1. The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology Center 1600.

2. The substitute specification filed 11/16/01 has been entered.

3. Claim 10 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed.

Applicant's arguments, filed 11/16/01, have been fully considered but have not been found convincing for the reasons of record set forth in Paper No. 9.

Applicant argues that the phrase "in the range of 6.5 Gy to 7.0 Gy" is not New Matter because the experiments on page 29 of the specification doses of 6.5 Gy and 7.0 Gy, and that Applicant may claim a range based upon specific examples as established in Ex parte Jackson 110 USPQ 561 (Bd. Pat. App. & Int. (1956)).

However, the phrase "in the range of 6.5 Gy to 7.0 Gy" does not meet the fact pattern found in Ex parte Jackson in which the range was based on all examples disclosed in application and *in which all elements recited in claim were present and would function.* In the instant case, while the species of 6.5 Gy and 7.0 Gy were found to support graft survival after hepatic portal administration, 6.0 Gy were insufficient (e.g., page 29, Group IV). The point at which this transition of insufficient dose to sufficient dose occurs is not disclosed in the specification. The phrase "*in the range of* 6.5 Gy to 7.0 Gy" does not limit the claims to only those points between and including 6.5 Gy and 7.0 Gy. Thus the instant claims do not recite ranges in which all elements recited in claim are present as functioning examples disclosed in the specification.

The rejection is maintained.

4. Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for effectively inducing immunotolerance in a mouse, does not reasonably provide enablement for larger organ transplant recipients, such as a human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's arguments, filed 11/16/01, have been fully considered but have not been found convincing for the reasons of record set forth in Paper No. 9.

Applicant argues that because the irradiation does is presented in grays (i.e., absorbed dose), the results of murine experiments would be directly applicable to human transplant, irrespective of body mass. Applicant further argues that no properties other than graft survival would be required for the skilled artisan to practice the instant invention in non-murine animals.

However, while Applicant's comments with respect to the absorbed dose are noted, there nevertheless does not appear to be sufficient direction to allow one of skill in the art to practice the instant invention in species other than mice with a reasonable expectation of success. Even when dose delivered is normalized between different species, the *response to that dose* is not the same. As Applicant acknowledges, there are differences between human and murine bone marrow cells in terms of radio-sensitivity. And as previously noted, in the absence of direction to experimental readouts that are reasonably predictive that a particular sublethal irradiation dose leads to graft survival; it would require undue experimentation, particularly in humans, to establish an effective irradiation dose based solely upon the end readout of graft survival. Therefore, the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

The rejection is maintained.